

REMARKS

Reconsideration is requested.

Claims 1, 17, and 20-23 are amended to clarify that the components recited in the claims are vertebroplasty injection and surgical components, in accordance with the Examiner's observations at pages 6-7 of the Final Rejection. Claims 22 and 23 are amended to clarify that the recited vertebroplasty injection and surgical components are those contained in *each tray*, as assumed by the Examiner for purposes of Examination. Claims 2-16, 18 and 19 are retained as previously presented. Claims now presented are Claims 1-23.

Argument

1: Rejection of Claims 22 and 23 as indefinite

Claims 22 and 23 were rejected as indefinite under 35 USC 112, second paragraph, because in the then-pending versions of those claims, the Examiner was not sure if the recited components were present collectively in both trays, or if each (the first and the second) tray contained the recited components. Claims 22 and 23 are amended to clarify that the components are those contained in each tray. The rejection should be withdrawn.

2: Rejection of Claims 17-19 as Anticipated by Lazarus

Claims 17-19 are rejected as anticipated by Lazarus, U.S. Patent 4,128,173. For the Lazarus patent to anticipate the claims, every element recited in these claims must be present in the Lazarus patent.

The Examiner does not take proper account of a point made in the Appeal Brief filed January 12, 2004, and reiterated in the last Amendment, namely that the "Lazarus apparatus does not have 'vertebroplasty injection components', recited in claim 17, lines 3 and 5, in either tray."

In construing terms in claims, the words used should be given their ordinary meaning to persons of ordinary skill in the art. Neither the Examiner nor the undersigned attorney is a person of ordinary skill in the art to which this invention pertains. The inventor, however, Dr. Kieran Murphy, is a person of more than ordinary skill in the art. Presented with the last Amendment was a Declaration Under 37 CFR 1.132, explaining that the Lazarus apparatus does

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not have “vertebroplasty injection components”, recited in claim 17, lines 3 and 5, in either tray, as that term is understood by persons of ordinary skill in the art. (See Declaration at pages 3-5, paragraphs 7-12.)

In response to Applicant’s previous amendment and the Declaration filed with the last Amendment, the Examiner repeats *verbatim* (page 5 of Final Rejection) a paragraph from page 5 of the Office Action of March 24, 2004, concluding that “it is clear that each tray [of Lazarus] include[s] a[n] injection component and they can perform a function in spinal surgery if one so desire[s].” The Examiner ignores the explanation in the Declaration why the Lazarus components are not “vertebroplasty injection components”, dismissing it as “opinion” of a party who has an interest in the outcome of the case, and lacking in “facts”. The Examiner ignores the facts recited in the Declaration in Paragraphs 7-12, *e.g.*, that vertebroplasty injection components are a different size than the Lazarus needles.

The Examiner then makes a point made previously, that the manner in which a device is to be employed does not differentiate the apparatus from prior art apparatus having the structural limitations. However, as explained in the Declaration, the recitation “vertebroplasty injection components” is more than an intended use; it designates for example needles sufficiently robust for injection of bone cement. The Examiner says “facts” are events, acts or occurrences which have actually taken place, and indeed, that is what *historical* facts are. However, it is also a fact, as pointed out in the Declaration, that vertebroplasty injection needles need to be sufficiently robust for injection of bone cement. So the Examiner ignores the facts stated in the Declaration, and *based on no facts at all*, elevates his own opinion over that of the expert. This is error.

The Examiner points out (page 7 of Final Rejection) that some of the items recited in Applicant’s claims are general surgical apparatus. The claims have been amended accordingly. Other items recited in Applicant’s claims, however, are vertebroplasty components, not taught or suggested by the applied references.

Accordingly, the rejection of Claims 17-19 should be withdrawn.

3: Rejections of Claims 1-16, 20 and 21 as Obvious from Vagley or from Vagley in view of eleven other references

Claims 1-16, 20 and 21 are rejected as obvious in view of Vagley, U.S. 6,158,437, and also as obvious in view of Vagley in view of eleven secondary references (Shanley, MacLeod et al., Smith et al., Arlers, Racz, Jiang et al., Singer, Draenert, Haynie, Hertzmann et al. and Baker).

The Examiner has used Appellant's claims as a shopping list to find patents that teach each *element* (or something he considers to be *like* each element) in the combination, but has not cited or applied a reference that teaches or suggests the *combination* itself.

Claims 1-16, 20 and 21 are directed to trays of vertebroplasty and surgical components for use in performing vertebroplasty. The Vagley patent discloses a tray and says things *other than* vertebroplasty components should be on the tray. So Vagley does not teach or suggest Applicant's combination, Vagley teaches a *different* combination.

The Declaration Under 37 CFR 1.132 filed with the last Amendment explains why the *combinations* claimed in Claims 1-16, 20 and 21 would not have been obvious to a person of ordinary skill in the art, either from Vagley alone or from Vagley in view of the eleven secondary references applied in another rejection. (See Declaration at page 5, paragraphs 13-14.)

In response to Applicant's previous amendment and the Declaration filed with the last Amendment, the Examiner says (pages 8-9 of Final Rejection) that Vagley discloses that his tray can be customized to cater to the preference of a specific surgeon. This does not amount to a teaching or suggestion of the *particular combinations* claimed by Applicant.

Accordingly, the rejections of Claims 1-16, 20 and 21 should be withdrawn.

4: Allowable Subject Matter

It is noted with appreciation that the Examiner has stated (page 10 of Final Rejection) that Claims 22 and 23 would be allowable if rewritten to overcome the rejections under 35 USC 112, and to include all of the limitations of the base claim (Claim 17; there are no intervening claims in the chains of dependency, as Claims 22 and 23 previously depended directly from Claim 17). Claims 22 and 23 have been so rewritten. Accordingly, they appear to be in condition for formal allowance.

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Conclusion

Reconsideration, withdrawal of the rejections, and allowance of all claims now presented, namely Claims 1-23, are courteously requested.

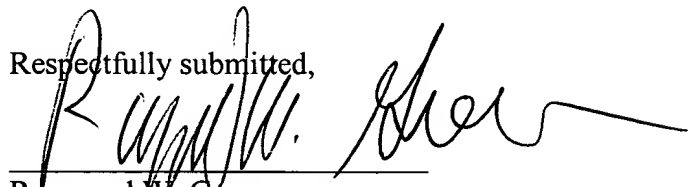
Claims 17-19, 22 and 23 recite "vertebroplasty injection components", which are not present in the Lazarus patent. Applicant has filed the Declaration Under 37 CFR 1.132 of the inventor, Dr. Kieran Murphy, showing that the Lazarus patent does not teach "vertebroplasty injection components" as that term is understood by persons of ordinary skill in the art.

Claims 1-16, 20 and 21 recite combinations, which neither Vagley nor any of the secondary references teach or suggest.

Claims 22 and 23 are indicated to be allowable if rewritten to overcome formal rejections and eliminate reference to rejected claims. Claims 22 and 23 have been so rewritten.

Accordingly, the Application appears to be in order for allowance, both as to form and in view of the prior art. Such action is courteously requested.

Respectfully submitted,



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